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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,073	04/19/2004	Rajiv Doshi	DOSHI.001C1	1880
25226	7590	07/13/2006	EXAMINER	
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			LOPEZ, AMADEUS SEBASTIAN	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/827,073

Applicant(s)

DOSHI, RAJIV

Examiner

Amadeus S. Lopez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-23 and 26-36 is/are pending in the application.
- 4a) Of the above claim(s) 26-34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-4, 8, 10, 11, 15-23, 35, and 36 is/are rejected.
- 7) ☒ Claim(s) 5-7 and 12-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by US

Patent No. 746,869 to Moulton.

2. With regards to claim 1, what is taught and shown by Moulton in Figs. 1-3 is a device for treating a patient with a breathing disorder, the device configured to fit substantially within a patient's mouth (Fig. 1; Col. 1, lines 38-41) and comprising at least one aperture (3) providing fluid communication between an inside an outside of the patient's mouth through the mouthpiece (Fig. 1), the device further comprising an obstructing member (2) configured to be held substantially within the patient's mouth (Fig. 1; Col. 1, lines 38-41) that obstructs at least a portion of the aperture, the obstructing member configured to limit exhalation air flow more than inhalation air flow through the aperture (Col. 2, lines 88-99; it is explained that the valve may be reversed in such a way as to allow a sufficient amount of air to be inhaled, while blocking air from being exhaled through the valve forcing the air to be expelled through the nose; therefore the valve is configured to limit exhalation air flow more than inhalation air flow through the aperture).

3. **With regards to claim 2**, what is taught and shown by Moulton in Figs. 1-3 is a device wherein it is configured to be used by a sleeping patient (Col. 1, lines 38-41).
4. **With regards to claim 3**, what is taught and shown by Moulton in Figs. 1-3 is a device configured to be held between a patient's jaws (Col. 1, lines 38-41).
5. **With regards to claim 4**, what is taught and shown by Moulton in Figs. 1-3 is a device wherein the obstructing member is configured to reduce an open area of the aperture by a pre-determined amount (Col. 2, lines 71-99; valve is configured to block the entire opening either in the exhalation or inhalation direction, which is the pre-determined amount).
6. **Claims 1-4, 8, 15, 20, 22, 35, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 774446 to Moulton.**
7. **With regards to claim 1**, what is taught and shown by Moulton in Figs. 1-5 is a device for treating a patient with a breathing disorder, the device configured to fit substantially within a patient's mouth (Fig. 1; Col. 2, lines 56-63) and comprising at least one aperture (8) providing fluid communication between an inside an outside of the patient's mouth through the mouthpiece (Fig. 1), the device further comprising an obstructing member (9 and 10) configured to be held substantially within the patient's mouth (Fig. 1; Col. 2, lines 56-63) that obstructs at least a portion of the aperture, the obstructing member configured to limit exhalation air flow more than inhalation air flow through the aperture (Col. 3, lines 1-41; it is explained that the valve may be reversed in such a way as to allow a sufficient amount of air to be inhaled, while blocking air from being exhaled through the valve forcing the air to be expelled through the nose;

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therefore the valve is configured to limit exhalation air flow more than inhalation air flow through the aperture).

8. **With regards to claim 2**, what is taught and shown by Moulton in Figs. 1-5 is a device wherein it is configured to be used by a sleeping patient (Col. 3, lines 1-9; device disclosed to prevent snoring and is therefore intended to be used by a sleeping patient).

9. **With regards to claim 3**, what is taught and shown by Moulton in Figs. 1-5 is a device configured to be held between a patient's jaws (Col. 2, lines 56-63).

10. **With regards to claim 4**, what is taught and shown by Moulton in Figs. 1-5 is a device wherein the obstructing member is configured to reduce an open area of the aperture by a pre-determined amount (Col. 3, lines 16-25).

11. **With regards to claim 8**, what is taught and shown by Moulton in Figs. 1-5 is a device for use in treating a patient with a breathing disorder, the device comprising a body (5) defining an inside surface (inside surface of plate 5 in contact with the teeth of the user) an outside surface (outside surface of plate 1 in contact with the lips of the user) and configured to fit substantially within a patient's mouth (Fig. 1); the body comprising an aperture (8) in a front portion thereof, the aperture providing fluid communication between the inside surface and the outside surface (Fig. 1); and a valve device (9 and 10) configured to be held substantially within the subject's mouth and further configured to limit expiratory fluid flow directed from the inside surface to the outside surface more than the inspiratory fluid flow from the outside to the inside surface (Col. 3, lines 1-41; it is explained that the valve may be reversed in such a way as to allow a sufficient amount of air to be inhaled, while blocking air from being exhaled

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through the valve, forcing the air to be expelled through the nose; therefore the valve is configured to limit exhalation air flow more than inhalation air flow through the aperture).

12. **With regards to claim 15**, what is taught and shown by Moulton in Figs. 1-5 is a device wherein the valve device comprises a movable element (9 and 10) pivotably (Fig. 1 and 5) joined to a fixed element (6) that is immovably attached to the body (5).

13. **With regards to claim 20**, what is taught and shown by Moulton in Figs. 1-5 is a device for treating a patient with a breathing disorder, the device comprising: a housing (comprised of plates 5, 6, 7, and clips 11) configured to be held in a patient's mouth (Fig. 1), the housing enclosing (Fig. 5) at least one valve (9 and 10) configured to create a first flow resistance to inspiration and a second flow resistance to expiration (Col. 3, lines 16-37; Moulton discloses that the volume of air admitted through the opening in the mouthpiece in the act of inhaling or expelled through said opening in the act of exhaling may be controlled at will by inserting the free end of one or both of the valves in the slot 15, so therefore the valves can inherently be configured to create a first flow resistance to inspiration and a second flow resistance to expiration).

14. **With regards to claim 22**, what is taught and shown by Moulton in Figs. 1-5 is a device wherein the valve (9 and 10) comprises a flap (Fig. 5).

15. **With regards to claim 35**, what is taught and shown by Moulton in Figs. 1-3 is a device for treating a patient with a breathing disorder, the device comprising a body (5) defining an inside surface an outside surface and configured to fit substantially within a patient's mouth; the body comprising an aperture (8) in a front portion thereof, and a valve device (9 and 10) configured so that at least a portion of the valve device is within

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the patient's mouth during inhalation and further configured to limit expiratory fluid flow directed from the inside surface to the outside surface more than inspiratory fluid flow from the outside of the inside surface.

16. **With regards to claim 36**, what is taught and shown by Moulton in Figs. 1-3 is the device wherein the valve device (9 and 10) is configured so that at least a portion of the valve device is positioned between the subject's lips during inhalation (Fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. **Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 774,446 to Moulton in view of 5865170 to Moles.**

18. **With regards to claim 10**, what is taught and shown by Moulton in Figs. 1-5 is a device with all the limitations of claim 10 with the exception of wherein the body is

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substantially u-shaped. What is taught and shown by Moles in Fig. 1 is a mouthpiece wherein the body is substantially u-shaped. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mouthpiece of Moulton to be substantially u-shaped as taught by Moles because Moles discloses that the u-shape of the body provides a resting place for a user's lips. "This resting place results in a more natural closure of the mouth thereby reducing fatigue on the diver's facial muscles (Col. 6, line 65 to Col. 7, line 9)."

19. With regards to claim 11, what is taught and shown by Moulton is a device with all the limitations of claim 11 with the exception of wherein the body comprises at least one concave channel configured to receive a patient's teeth. What is taught and shown by Moles in Fig. 1 is a mouthpiece wherein the body comprises at least one concave channel configured to receive a patient's teeth. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Moulton to have a body comprising at least one concave channel (28) configured to receive a patient's teeth because this concave channel allows the mouthpiece or body to conform more comfortably to the shape of the diver's teeth and actually assists in gripping the diver's teeth thereby reducing muscle fatigue and the diver's gag reflex (Col. 6, lines 43-64).

20. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 774446 to Moulton.

21. With regards to claim 16, what is taught by Moulton in Figs. 1-5 is a device with all the limitations of claim 16 with the exception of wherein the movable element (9 and

10) are joined to the fixed element (6) by a hinge with a pivot axis lying in a plane substantially parallel to the outside surface. What is taught by Moulton is slitting the outer plate surface (5) with the two ends formed acting as a valve element to the opening 8 by pivoting about the outer plate from where it was slit. After reviewing the specification the applicant never discloses any criticality for utilizing a valve comprising a moving element joined to a fixed element by a hinge with a pivot axis lying in a plane substantially parallel to the outside surface. Therefore it would have been an obvious matter of design choice to utilize a valve with a movable element pivotably joined to a fixed element as taught by the applicant or any other means of regulating airflow through an aperture such as that taught by Moulton that would be effective in regulating airflow in the exhalation and inhalation directions.

22. **With regards to claim 17**, what is taught and shown by Moulton in Figs. 1-5 is a device wherein the movable element (9 and 10) comprises a flap (Fig. 3 and 5) that occludes at least a portion of the aperture (8).

23. **With regards to claim 18**, what is taught and shown by Moulton in Figs. 1-5 is a device wherein the flap (9 and 10) is secured to the fixed element (6) so as to allow the flap to pivot only inwards (Col. 3, lines 9-16; when plate 5 is reversed).

24. **With regards to claim 19**, what is taught and shown by Moulton in Figs. 1-5 is a device wherein the flap (9 and 10) is made of a substantially flexible material (Col. 2, lines 56-76).

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Conclusion

25. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure. US 4862903.

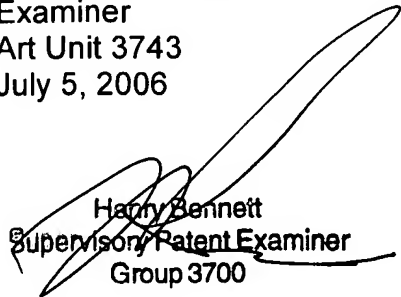
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Amadeus S Lopez
Examiner
Art Unit 3743
July 5, 2006

ASL


Henry Bennett
Supervisor, Patent Examiner
Group 3700